DETAILED ACTION

This action is responsive to the application filed 8/8/2006.

Priority

1. Priority is claimed to PCT/IL05/00163 filed 2/9/2005 which claims priority to provisional application 60/554459 filed 2/12/2004 and to provisional application 60/572283 filed 5/17/2004.

Information Disclosure Statement

2. The information disclosure statement filed 3/26/2007 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. No copy of WO 99/32950 is provided and will not be considered.

Drawings

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: (98) described in the specification (paragraph [0076] of the PG Pub version of the specification) is not present in Fig. 6A. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to

avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 20, 22, and 43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. The terms "low power level" and "high power level" in claims 20 and 43 are unclear as "low" and "high" are relative terms. The terms "low power level" and "high power level are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

7. Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. Claim 22 recites an intended use

of controlling a flow of emboli in an aorta of a patient but the recited elements of claim 22 fail to include the intended use feature.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1, 3-4, 6-7, 9-21, 29, 31-33, and 35-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Milo (WO 01/41655 dated 6/14/2001) hereinafter Milo.

10. Addressing claims 1 and 29, Milo discloses a device and method for controlling a flow of emboli in an aorta of a patient, the device comprising: an ultrasonic transducer, which is configured to transmit an ultrasonic beam into the aorta in a vicinity of a great origin of a neck vessel (see entire document, particularly p. 14 lines 1-31 and p. 19 line 23-p. 20 line 10); and a driver circuit, which is coupled to drive the ultrasonic transducer to generate the ultrasonic

beam at a frequency and power level sufficient to divert at least a target fraction of the emboli of a given type and size away from the neck vessel (see p. 14 lines 1-31 and p. 19 lines 9-22).

11. Addressing claims 3 and 31, Milo discloses wherein the ultrasonic transducer is configured to transmit the ultrasonic beam so as to divert at least the target fraction of the emboli into the descending aorta (see p. 14 lines 1-31).

12. Addressing claim 4, Milo discloses a holder, which is coupled to hold the ultrasonic transducer in proximity to the aorta (see p. 14 lines 1-31).

13. Addressing claims 6 and 32, Milo discloses wherein the holder is configured to hold the ultrasonic transducer on an anterior side of the aorta, so that the ultrasonic transducer transmits the ultrasonic beam in a posterior direction through the aorta (see p. 14 line 32-p. 15 line 9).

14. Addressing claims 7, 9, 33, and 35, Milo discloses wherein the ultrasonic beam is unfocused (see p. 14 lines 1-31) and wherein the ultrasonic beam diverges from the transducer through the aorta (see p. 14 lines 1-31).

15. Addressing claims 10-15 and 36-40, Milo discloses a flexible coupler interposed between the transducer and the aorta, wherein the flexible coupler comprises at least one of a gel and a polymer, wherein the flexible coupler comprises a membrane, which contains a fluid for coupling the ultrasonic beam from the transducer to the aorta (see p. 19 line 23-p. 20 line 10), a housing, which contains the transducer and the fluid, wherein the membrane forms at least part of the housing, the housing comprising a fluid port for injecting the fluid into the housing while the transducer is fixed in proximity to the aorta, and a fluid

circulation assembly coupled to the fluid port so as to cool the transducer by passage of the fluid through the housing, wherein the fluid circulation assembly comprises a closed circuit (see p. 19 line 23-p. 20 line 10 and fig. 11).

16. Addressing claims 16-17, Milo discloses an acoustic waveguide, which is adapted to convey the ultrasonic beam from the ultrasonic transducer to the aorta, wherein the acoustic waveguide has a distal end, which is configured to be brought into proximity with the aorta, and comprises a diverging optic in a vicinity of the distal end (see p. 19 line 23-p. 20 line 10 and fig. 11).

17. Addressing claim 18-21 and 41-44, Milo discloses wherein the driver circuit is adapted to actuate the ultrasonic transducer intermittently, responsively to variations in the flow of the emboli into the aorta (see p. 9 lines 9-27), wherein the driver circuit is coupled to receive an indication of a heartbeat of the patient, and to actuate the ultrasonic transducer in synchronization with the heartbeat (), wherein the driver circuit is adapted to actuate the ultrasonic transducer at a low power level during a first time period and at a high power level during a second time period, responsively to a variation in the flow of the emboli into the aorta associated with the second time period (see p. 9 line 28-p. 10 line 13), and wherein the driver circuit is operative to actuate the ultrasonic transducer with pulsed excitation (se p. 10 line 14-p. 11 line 11).

18. Claims 23-26 and 28 are rejected under 35 U.S.C. 102(e) and 102(a) as being anticipated by Diederich et al. (US 2003/0216721 published Nov. 20, 2003 and filed Jan 15 2003) hereinafter Diederich.

19. Addressing claim 23, Diederich discloses an ultrasonic assembly, comprising: an ultrasonic transducer, which is configured to transmit an ultrasonic beam (see whole document specifically fig. 3B and paras 245-247); housing, which contains the ultrasonic transducer and comprises a coupler for coupling the ultrasonic beam into a target tissue (see paras 66); cabling, having distal and proximal ends, the distal end coupled to the housing and comprising an electrical cable and fluid tubing (see fig. 3B and para 246); and a cassette coupled to the proximal end of the cabling, the cassette comprising: an electrical connector coupled to the electrical cable and adapted to be coupled to a power source for driving the transducer (see figs. 3B and 17A-B and paras 246 and 277-279); and a fluid reservoir coupled to the fluid tubing and containing a fluid for circulation through the housing via the tubing in order to cool the transducer (see figs. 3B and 17A-B and paras 246 and 277-279).

20. Addressing claims 24-26 and 28, Diederich discloses a console having a receptacle sized to receive the cassette, the console containing the power source for engaging the electrical connector and a mechanical drive for driving the circulation of the fluid, wherein the console is adapted to drive the circulation of the fluid without contacting the fluid, which flows in a closed circuit through the tubing, wherein the console comprises a cooling device, which is positioned to thermally engage the fluid reservoir when the cassette is inserted in the receptacle, wherein the fluid reservoir and tubing are filled with the fluid and then hermetically sealed and sterilized before use of the assembly (see figs. 3B and 17A-B and paras 246 and 277-279).

Claim Rejections - 35 USC § 103

21. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

22. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

23. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

24. Claims 2, 8, 30 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Milo.

25. Addressing claims 2, 8, 30 and 34, Milo discloses all the above limitations. Milo does not explicity disclose wherein the ultrasonic frequency and power level are sufficient to reduce the flow of the emboli of the given size and type into the neck vessel by at least 80% or wherein the ultrasonic beam has an intensity in the aorta of at least 0.3 W/cm^2. However, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of invention to find an optimum frequency and power level, including those in the instant claims, to achieve a more desired outcome to the procedure. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); see also *Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382; *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969). For more recent cases applying this principle, see *Merck & Co. Inc. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), *cert. denied*, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

26. Claims 5 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Milo, in view of Ng (US 5820623 dated Oct 13 1998), hereinafter Ng.

27. Addressing claims 5 and 22, Milo discloses the above limitations of claims 1 and 4. Milo discloses the above device is used during a cardiovascular

surgery, namely open-heart surgery (see abstract and p. 2 lines 33-35). Milo does not explicitly disclose using a retractor.

28. However, Ng discloses a retractor used to support and position medical tools, namely an ultrasonic probe since ultrasound probes need to be moved at fixed and accurate intervals (see col. 8 lines 42-52).

29. Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art to modify Milo by adapting the ultrasound holder to be fixed to a retractor used to spread a sternum of the patient during open heart surgery, and the holder having a distal end that is coupled to hold the ultrasonic transducer in proximity to the aorta so that the transducer transmits the ultrasonic beam into the aorta during the surgery as taught by Ng since ultrasound probes need to be moved at fixed and accurate intervals or accurate operation.

30. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Diederich in view of Jandrell (US 2003/0137450 filed Jan 7 2003) hereinafter Jandrell.

31. Addressing claim 27, Diederich discloses all the above limitations. Diederich discloses wherein the cassette comprises an electronic device containing data regarding the assembly (see figs. 3B and 17A-B and paras 246 and 277-279), but does not explicitly disclose wherein the console comprises a wireless reader, which is coupled to read the data from the electronic device when the cassette is inserted in the receptacle.

32. Jandrell discloses a wireless reader, which is coupled to read data from an electronic device when a cassette is inserted in the receptacle (see paras 37-41).

33. Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of invention to include into Diederich the console comprises a wireless reader, which is coupled to read the data from the electronic device when the cassette is inserted in the receptacle as taught by Jandrell to enable data to be transferred without bulky cables.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIGEL FONTENOT whose telephone number is (571)270-7032. The examiner can normally be reached on Monday-Friday (7:00a-4:00p).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. F./
Examiner, Art Unit 3768

/Unsu Jung/
Primary Examiner, Art Unit 1641